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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/872,527	06/11/1997	YAJUN GUO	225/273	9637

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/872,527	GUO, YAJUN	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *103,107-119,121-124,126-142,144 and 145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *103,107-119,121-124,126-142,144 and 145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/03 has been entered.

2. Applicant's amendment filed 11/28/03 is acknowledged and has been entered.

3. Applicant is reminded of Applicant's election of the species of hepatocellular carcinoma cells, 4-1BB positive cells, antibodies against 4-1BB positive cells, TNF-alpha treated cells and INF-gamma treated cells and TNF-alpha and INF-gamma in Paper No. 34 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 103, 107, 110-115, 118, 119, 121-124, 126-137 and 140-142 read on the elected species enunciated above.

Upon consideration of the prior art, the search has been extended to include the species recited in instant claims 108-110, 116, 117, 138 and 139.

Claims 103, 107-119, 121-124, 126-142, 144 and 145 are currently being examined.

4. The disclosure is objected to because of the following informalities:

Applicant is required to amend the specification (i.e., paragraph spanning pages 31 and 32) to disclose the name and address of the depository for the cell lines disclosed in the said paragraph.

Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 137, 138 and 139 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to make and/or use the instant invention. The claimed composition comprising hepa 1-6 hepatocellular carcinoma cells, EL-4 cells or SMCC-1 cells. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a composition which comprises a cell line designated "hepa 1-6", "EL-4" or "SMCC-1". The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be made and/or used.

The specification discloses working examples of compositions comprising HEPA 1-6 hepatocellular carcinoma cells, EL-4 lymphoma cells and SMCC-1 colon carcinoma cells, said cells being armed with anti-CD28:gp55 monoclonal antibody (Examples 6.2-6.7) and use in mice. The specification further discloses on page 29 at lines 25-28 that "Hepa 1-6 is a chemically induced hepatoma originating in a C57BL/6 mouse (G. J. Darlington et al., 1980, J. Natl. Cancer Inst. 64: 809)." The specification further discloses on page 46 at lines 10-11 that all publications referenced are incorporated by reference herein..." The specification discloses on page 40 at lines 10-15 that the EL-4 lymphoma and SMCC-1 colon carcinoma cell lines grow rapidly and develop subcutaneous tumors in syngenic C57 BL/6 mice and further discloses "(see for example, Li et al., 1996, J. Exp. Med. 180: 211)".

The specification does not appear to disclose whether the said Hepa 1-6 hepatoma cells, EL-4 cells or SMCC-1 cells are readily available to the public, nor does the specification disclose a repeatable method for obtaining the said cells. It is apparent that the said cells are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If the said cells are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the relevant cell lines. See 37 CFR 1.802.

There is insufficient guidance in the specification as to how to make and/or use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 103, 107-119, 121-124, 126-142, 144 and 145 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 137 is indefinite in the recitation of "hepa 1-6 cells" because the characteristics of the said cells are not known. The use of "hepa 1-6" as the sole means of identifying the cells renders the claim indefinite because "hepa 1-6" is merely a laboratory designation which does not clearly define the claimed product.

b. Claim 138 is indefinite in the recitation of "EL-4 cells" because the characteristics of the said cells are not known. The use of "EL-4 cells" as the sole means of identifying the cells renders the claim indefinite because "EL-4 cells" is merely a laboratory designation which does not clearly define the claimed product.

c. Claim 139 is indefinite in the recitation of "SMCC-1" because the characteristics of the said cells are not known. The use of "SMCC-1" as the sole means of identifying the cells renders the claim indefinite because "SMCC-1" is merely a laboratory designation which does not clearly define the claimed product.

d. Claims 131 and 133 are indefinite in the recitation of "wherein said composition comprises two or more gp55, gp95 or gp210 binding antibodies" because it is not clear what is meant, i.e., if the said composition comprises two antibodies of the same specificity or two antibodies of different specificities. It is not clear if what is meant is, wherein said composition comprises two or more antibodies selected from the group consisting of gp55, gp95 and gp210. For example, the language recited in claim 133 encompasses two antibodies of the same specificity binding to two different molecules of gp55.

e. Claim 103 is indefinite in the recitation of "irradiated and treated in vitro wherein" because it is not clear what is meant, i.e., if it is meant that cells which have been irradiated and treated in vitro to express...".

f. Claims 108 and 109 are indefinite in the recitation of "said one or more hepatocellular carcinoma, lymphoma or colorectal carcinoma cells comprise one or more". There is insufficient antecedent basis for this limitation in the claim.

g. Claims 116 and 117 are indefinite in the recitation of "wherein the one or more target hepatocellular carcinoma, lymphoma or colorectal carcinoma cells". There is insufficient antecedent basis for this limitation in the claim.

h. Claim 110 is indefinite in the recitation of "said one or more CD28 or 4-1BB molecules comprise one or more CD28 molecules". There is insufficient antecedent basis for this limitation in the claim.

9. Claim 145 is objected to for the recitation of "4-1BB L" which appears to be a typographical error. It is suggested that Applicant amend said claim to recite "4-1BB".

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 103, 107, 110-115, 118, 119, 121-124, 126-137, 140-142, 144 and 145 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 70-74, 81, 84, 86-95, 99 and 102-110 of copending Application No. 09/216,062. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the 09/216,062 application encompass the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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